



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,870	01/09/2004	Thomas Adam Alheidt	P-5860	8649

26253 7590 03/20/2007
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

HUH, BENJAMIN

ART UNIT	PAPER NUMBER
----------	--------------

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/754,870	Applicant(s) ALHEIDT, THOMAS ADAM	
	Examiner Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
 4a) Of the above claim(s) 16-22 and 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/11/05 & 1/9/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species I: Figures 1-7 which reads on claims 1-15 & 23-25 in the reply filed on 12/21/06 is acknowledged.

Information Disclosure Statement

The information disclosure statement filed 5/11/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, & 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Grimard (US Patent No. 5795337). The Grimard reference discloses a syringe assembly in figures 1-12 comprising a barrel 40 including a cylindrical side wall having an inside surface defining a chamber for retaining fluid, an open proximal end and a

distal end including a distal wall with an elongate tip 52 extending distally therefrom having a passageway therethrough in fluid communication with said chamber; a plunger 33 including an elongate body portion having a proximal end, a distal end and a resilient stopper 20 slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel; wherein fluid is moved distally in said passageway after fluid has been delivered from said chamber and said stopper is in contact with said distal wall.

With respect to claim 3, see figure 2 & 6.

With respect to claim 14, see col. 4 lines 46-57.

With respect to claim 15, see figures 5-6.

Claims 1, 3, 11, & 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Grimard et al (US Patent No. 5899881). The Grimard reference discloses a syringe assembly in figures 1-12 comprising a barrel 100 including a cylindrical side wall having an inside surface defining a chamber for retaining fluid, an open proximal end and a distal end including a distal wall with an elongate tip extending distally therefrom having a passageway therethrough in fluid communication with said chamber; a plunger including an elongate body portion having a proximal end, a distal end and a resilient stopper 200 slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by

movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel; wherein fluid is moved distally in said passageway 108 after fluid has been delivered from said chamber and said stopper is in contact with said distal wall.

Claims 1-10 & 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Shadd, Jr. (US Patent No. 6053894). The Shadd reference discloses a syringe assembly in figures 1-3 comprising a barrel 12 including a cylindrical side wall having an inside surface defining a chamber for retaining fluid, an open proximal end and a distal end including a distal wall with an elongate tip 16 extending distally therefrom having a passageway therethrough in fluid communication with said chamber; a plunger (40, 44, 38) including an elongate body portion having a proximal end, a distal end and a resilient stopper, seen as elements 30 & 36, slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel; wherein fluid is moved distally in said passageway after fluid has been delivered from said chamber and said stopper is in contact with said distal wall.

With respect to claim 2, wherein the stopper has a distal end and a proximal end which has a cavity wherein the plunger is connected to a complementary detent structure created by the proximal end of 30 in conjunction with elements 44 & 38 of the

plunger. Wherein the first detent position is seen as figure 2 and the second position as seen in figure 3.

With respect to claim 3, wherein the angle changes due to the pressure and location of element 36.

With respect to claim 4, a distally directed projection 36 which is seen to be on the distal end which is shaped to fit in the passageway, see figure 3.

With respect to claim 5, the protuberance seen as the proximal end of 30.

With respect to claims 6-10, see figures 2 & 3.

With respect to claim 14, col. 2 lines 42-51.

With respect to claim 15, cannula 28 in figures 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grimard et al (US Patent No. 5899881) or Shadd, Jr. (US Patent No. 6053894) in view of Caizza et al (US Patent No. 5807374) or Odell et al (US Patent No. 6361524). Even though Grimard and Shadd do not explicitly disclose a tip cap attention is directed to Caizza and Odell. The Caizza and Odell reference teach the use of caps for maintaining the sterility of the syringe before use and during transport. Therefore, it would have been

obvious to one of ordinary skill in the art at the time of the invention to modify the device of Grimard or Shadd with the teachings of Caizza or Odell in order to maintain sterility and to prevent inadvertent punctures.

Claims 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Grimard et al (US Patent No. 5899881). Even though the Grimard reference does not explicitly disclose the use of saline or heparin flush, the use of these two flush solutions are well known in the art. Since Grimard already mentions the use of flush agents in the reference, one skilled in the art would have incorporated saline or heparin into the invention of Grimard.

Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shadd, Jr. (US Patent No. 6053894) as applied above in view of Grimard et al (US Patent No. 5899881) and further in view of Caizza et al (US Patent No. 5807374) or Odell et al (US Patent No. 6361524). The Shadd reference discloses a barrel 12 with an elongate tip 16, a plunger (40,44,38) and a resilient stopper (30,36), a complementary detent structure with a first and second position, figures 2-3 respectively, as described in the rejection above. Now even though Shadd does not explicitly disclose a quantity of flush solution attention is directed to Grimard. The Grimard reference teaches the use of a flush solution for flushing the syringe or other items. Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Grimard to incorporate the use of a flush solution into the device of Shadd in order to

flush a syringe or an IV. Now even though Shadd does not explicitly disclose a tip cap, attention is directed to Caizza and Odell. The Caizza and Odell reference teach the use of caps for maintaining the sterility of the syringe before use and during transport. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Grimard or Shadd with the teachings of Caizza or Odell in order to maintain sterility and to prevent inadvertent punctures.

With respect to claim 24, see figure 3, projection 36 while in second detent position.

With respect to claim 25, wherein the protuberance is seen to be the proximal end of 30.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BH#

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons